Request for Proposals (RFP):
Laboratory Information System (LIS)

Application Due Date: October 31, 2023

Technical Assistance Webinar: October 6, 2023

Submit to: Hewan Moges, Specialist, Global Health, hewan.moges@aphl.org

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SUMMARY

The Association of Public Health Laboratories (APHL) received funding through a cooperative agreement with the U.S. Centers for Disease Control and Prevention (CDC) to implement a laboratory information system (LIS) at the Georgian Public Health Laboratories with support from the Georgian National Center for Disease Control (NCDC) surveillance program.

BACKGROUND

This RFP solicits offers from qualified information technology software providers with offices and operations in Georgia/Central Asia/European region to implement an LIS at laboratories that fall under the purview of NCDC Georgia. The successful proposal will provide a cost-effective LIS that can be implemented in a timely manner, is reliable, scalable, and will offer an affordable solution that can be sustained in a resource-constrained setting. Proposals should clearly state the plan and means for providing operational support on an on-going basis directly by the provider or through an identified local company with the knowledge and capacity to provide support. Computer and network hardware including barcode scanners and label printer procurement will be the responsibility of APHL and/or NCDC Georgia and do not have to be factored into the proposal by the LIs provider.

Phase 1 will provide objective information for development of a national plan for LIS implementation that addresses the technical, human resource, support and financial issues for a LIS. The project award may be made with an option for the successful provider to continue to rollout the LIS to additional sites including all 7 laboratories in Phase 2 if the proposal describes favorable licensing fees and innovative options for controlling maintenance costs.

APHL, working together with the Georgia MOH and US CDC, surveyed the NCDC laboratories that will be included in the Phase 1 implementation of the LIS in Georgia. We request a detailed budget for Phase 1 and high-level estimation for Phase 2 deployment. APHL expects to award a contract for this project by February 12, 2024.

APHL assisted US CDC and the Georgia NCDC in the performance of a needs assessment for an LIS at NCDC. The assessment team activities included the following:

- Survey of operations at NCDC laboratories and meetings with stakeholders, in order to describe standard laboratory services and current LIS capacity in the public health laboratory sector of Georgia;
- Visits to the different tiers of public health laboratories to compare sample workflow procedures and understand how samples are processed;
- Discussion meetings on LIS requirements with Georgia NCDC surveillance leadership and MOH Information Technology Agency (ITA), as well as US CDC Georgia staff and leadership;
- Compiled the specific information, request and report forms and requirements for the development of an RFP for the identification of an appropriate LIS application.

RFP PROCESS OVERVIEW

- This LIS application should be considered a laboratory-oriented, sample-centric application as opposed to a patient-centric, patient management application. While there are many patient-centric applications that have laboratory components, the primary purpose of this application is to collect and manage clinical, surveillance and environmental laboratory test data, quality

control data, inventory management data, and training information within the laboratory. Sample-centric laboratory systems that link individual patient data through some universal identifier for epidemiological purposes are preferred.

- For the purpose of this RFP, the LIS vendor should describe the approach and technical specifications and ability to deploy LIS as:
    - Central database deployment hosted by a private cloud or at primary Georgia NCDC location. The centralized LIMS deployment should ensure there is an appropriate security grouping that offers system demarcation for the laboratories that will be added in Phase 2. The NCDC will need the ability to manage data from all laboratories.
- The laboratory requirements found in section 6, Laboratory Business Requirements, are meant to be a guide for responding to this RFP and to ensure that respondents understand the type of data that needs to be collected and communicated within the Georgia laboratories. Consequently, they are general in nature and represent the minimum of data points to be collected.
- Computer and network hardware procurement will be the responsibility of APHL and/or NCDC Georgia. Respondents can assume that:
    a. Network cable will be in place and functional in each laboratory prior to installation of the application.
    b. Each laboratory will have access to high speed internet and that the access will be available through the local LAN installed in the laboratory.
    c. Sufficient PC's will be available to run the application software in each laboratory prior to the installation of the application.
    d. Bar code printers and scanners (if necessary) along with a sufficient number of networked system printers required by the selected application will be available prior to the installation of the application.
- Deployment will occur in three phases and include data exchange and electronic laboratory reporting. As a result, applications that have the ability to create and transmit data files in internationally recognized standards such as HL7 and utilize standard vocabulary code sets such as LOINC and SNOMED are preferred.
    a. Phase 1 will take place at NCDC in Tbilisi, Georgia. This will involve two aspects:
        i. Installation and deployment of the LIS at the Reception, Virology, Serology, Molecular Biology, Bacteriology, and Quality Assurance sections
        ii. Data exchange with EIDSS surveillance system
    b. Phase 2 will deploy the LIS at 3 zonal and 4 local laboratories. It will include capability to refer specimens from lower tier laboratories to higher tier and return of results electronically .
    c. Phase 3 is expected to include expansion of the LIS to add additional features that are a low priority for Phase 1. This includes, but is not limited to, installation of an LIS module for the Chemistry, Parasitology, Bacteriology, and Specimen archiving sections.
- Respondents whose application software is licensed by PC or server, can base their proposal on the following standard information:
    a. LIS Central Server hosted by private cloud or at the Georgia NCDC
- Respondents should bid a LIS application package that includes the following for Phase 1:
    a. All software required to make the LIS viable at NCDC
    b. A browser or web-based LIS that does not require installation on individual PCs
    b. Instrument Interfaces for existing instrumentation at NCDC
    c. Either a commercial or open-source LIS will be considered though the proposal for an open-source LIS must include a model for configuration/customizing, implementation, training and support that will be the responsibility of the LIS provider

c. Super user, end user and network administrator training (if applicable). We recommend an initial minimum of one week user training at the laboratory facility on the software as provided, and two weeks post-live supportive supervision.
d. Distribution of software user manual and release notes to end users at NCDC.
d. Installation, validation, and initial customization of the software for use in Phase 1 sites
e. One (1) year minimum of software maintenance (updates, patches, etc.)
f. One (1) year minimum of software support (for user questions, help desk, etc.). The maintenance and support may be a combined package
g. Plans and prices for the continuation of software maintenance and support
h. Costs associated with instrument interfaces
i. Costs associated with technical support (if not included with software maintenance and support)
j. Costs associated with additional training besides those listed above and software customization following initial installation.

Questions regarding technical and business (laboratory) requirements described in this RFP must be directed in writing, via email to Matthew McCarroll

Matthew McCarroll
Lead Specialist for Global Health, APHL
Email: matthew.mccarroll@aphl.org

DURATION OF AWARDS

The initial award will be made through September 29, 2024. Any subsequent awards will be made during the following financial year for APHL's cooperative agreement with CDC contingent upon funding received.

ELIGIBLE APPLICANTS

This RFP solicits offers from software providers that can meet the following criteria

1. Have offices and operations in Georgia, Central Asia, and/or European region
2. LIS providers can share examples of successful deployment and use of the LIS in at least 3 public health laboratories.
3. The LIS user interface as well as maintenance and support can be provided in Georgian and English.

PROGRAM EXPECTATIONS

The notes here on deployment approach, assumptions and preferences, while not requirements, provide an overview of important issues for consideration by respondents.

1. This LIS application should be considered a laboratory-oriented, sample-centric application as opposed to a patient-centric, patient management application. While there are many patient-centric applications that have laboratory components, the primary purpose of this application is to collect and manage clinical, surveillance and environmental laboratory test data, quality control data, inventory control data, and training information within the

laboratory. Sample-centric laboratory systems that link individual patient data through a universal identifier for epidemiological purposes are preferred.

2. For the purpose of this RFP, the LIS vendor should describe the approach and technical specifications and ability to deploy LIS as:
    - Central database deployment hosted by a private cloud or at primary Georgia NCDC location. The centralized LIMS deployment should ensure there is an appropriate security grouping that offers system demarcation for the laboratories that will be added in Phase 2. The NCDC will need the ability to manage data from all laboratories.

3. The laboratory requirements found in section 6 Laboratory Business Requirements are meant to be a guide for responding to this RFP and to ensure that respondents understand the type of data that needs to be collected and communicated within the Georgia laboratories. Consequently, they are general in nature and represent the minimum number of data points to be collected.

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    c. Sufficient PC's will be available to run the application software in each laboratory prior to the installation of the application software.
    d. Bar code printers and scanners (if necessary) along with a sufficient number of networked system printers required by the selected application will be available prior to the installation of application software.

5. Deployment will occur in three phases and include data exchange and electronic laboratory reporting. As a result, applications that have the ability to create and transmit data files in internationally recognized standards such as HL7 and utilize standard vocabulary code sets such as LOINC and SNOMED are preferred.
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    c. Phase 3 is expected to include expansion of the LIS to add additional features that are a low priority for Phase 1. This includes, but is not limited to, installation of an LIS module for the Chemistry, Parasitology, Bacteriology, and Specimen archiving sections.

6. Respondents whose application software is licensed by PC or server, can base their proposal on the following standard information:
    a. LIS Central Server hosted by private cloud or at the Georgian MOH

7. Respondents should bid a LIS application package that includes the following for Phase 1:
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Matthew McCarroll
Lead Specialist for Global Health, APHL
Email: matthew.mccarroll@aphl.org

LETTER OF INTENT

Not required

SUBMISSION OF RFP

Responses must be sent to APHL by e-mail attachment in MSWord or PDF format (electronic signatures accepted) to Hewan Moges at hewan.moges@aphl.org.. E-mail attachment is the preferred means of receipt. E-mail responses must be received by 5 pm (U.S. eastern time) on October 31, 2023. Submitters will receive a confirmation of receipt of their proposal by APHL. APHL may terminate or modify the RFP process at any time during the response period.

Responses that are not received by the stated deadline shall be determined to be non-responsive and at APHL's discretion may not be considered in the review of respondents.

Vendor information required to be included with response.

1. Full legal name and if LIS provider has a "doing business name" the d/b/a as well.
2. Authorized representative of the Contractor for the proposal.

3. Telephone, fax and e-mail address of the single point of contact for communication between APHL and the LIS provider. Contact information for other persons whom the LIS provider may request informational copies sent in addition to the single point of contact.
4. Business mailing address.

TRAVEL

The LIS provider does not have to include travel in the costing estimate as APHL will be responsible for arranging the travel. APHL does require an estimate of the number and duration of trips expected.

EVALUATION OF RESPONSES

There are three parts of the review for the award of this contract by APHL.

Initial Review

Part One:
APHL reviews all responses received by the response deadline, assesses the responses with the Georgia NCDC & CDC-Georgia and compares them to the requirements stated in the RFP.

One or more providers are selected to be included in Part Two of the RFP review process. Applications that do not meet the minimum technical requirements of the RFP may not be included for consideration in Part Two due to weaknesses in the noted criteria compared to other applications. Respondents to the RFP should address all noted criteria.

Part Two:
APHL may require respondents selected for the Part Two review to provide virtual demonstration of their proposed application to APHL, CDC-Georgia and the Georgia NCDC managers and representatives and answer questions related to their software, and project plan.

Part Three:
After consideration of the information provided in the RFP response and a demonstration of the application, Georgia NCDC shall select the preferred respondent in consultation with APHL and CDC-Georgia. APHL will request a final offer from the preferred respondent prior to awarding a contract.

The final offer will permit inclusion of changes that may arise in deliverables or conditions of the implementation during the negotiation of a contract.

The purchasing contract negotiated between APHL and the selected respondent will identify costs and payments to be associated with:

- initial system licenses
- purchase price
- implementation costs
- training costs
- maintenance and update costs
- other associated costs and services.

Evaluation Team

The initial screening will be conducted by APHL to ensure applications meet the minimum requirements stated in the RFP. The final selection will be made by Georgia NCDC.

Evaluation Criteria

Responses are assessed on these criteria:

- LIS Phase 1 Project requirements
- Strength of the provider's project plan to successfully implement a LIS at NCDC.
- Strength of the providers project plan to sustain operation of LIS at NCDC
- Value of the offer relative to cost, performance and maintenance

TERM OF PROJECT

Detailed contract and terms will be finalized as part of contract negotiations. The contract starting and ending effective dates shall be indicated on the purchase order or contract and by mutual agreement of both parties; the ending date may be extended for maintenance, support and additional work subject to the APHL and CDC cooperative agreements requirements.

AWARD ANNOUNCEMENT

The bidders' conference will take place between November 27, 2023 and December 1, 2023. APHL will inform selected and non-selected applicants of the award decision by December 18, 2023. APHL will post information on the RFP on APHL's procurement website, www.aphl.org/rfp. The expected date of contract award is February 12, 2024.

All applicants will be entitled to utilize APHL's RFP Appeals Process to formulate an appeal regarding alleged irregularities or improprieties during the procurement process. Specific details of this policy are located on the procurement website.

CONDITIONS OF AWARD ACCEPTANCE

The eligible applicants must be able to contract directly with APHL or have an existing relationship with a third-party organization that can contract directly with APHL on behalf of the applicant.

DISCLAIMER AND OTHER GENERAL MATTERS

This RFP is neither an agreement nor an offer to enter into an agreement with any respondent. Once evaluation is complete, APHL may choose to enter into a definitive contract with the selected RFP applicant(s).

APHL must ensure that the selected applicant(s) are neither suspended nor excluded from receiving federal funds and that the applicant(s) meet any other funding eligibility requirement imposed by the Cooperative Agreement. APHL's determination of whether the applicant is eligible to receive Cooperative Agreement funding will be definitive and may not be appealed. In the event that APHL determines that the selected applicant(s) is ineligible to receive Cooperative Agreement funding, APHL will nullify the contract or will cease negotiation of contract terms.

Each applicant will bear its own costs associated with or relating to the preparation and submission of its application. These costs and expenses will remain with the applicant, and APHL will not be

liable for these or for any other costs or other expenses incurred by the applicant in preparation or submission of its application, regardless of the conduct or outcome of the response period or the selection process.

RESPONSE REQUIREMENTS

Respondents must provide a point-by-point response to each General Requirement specified in this RFP. For each requirement, respondents should provide documentation as requested. The documentation demonstrates they understand the requirement and agree to the requirement. Responses to general requirements must be in the same sequence and numbered as they appear in this RFP.

1. **Executive Summary**

Provide a narrative summary of the proposal being submitted. The summary should identify all product(s) and / or service(s) that are being offered in the proposal.

2. **Organization / Management Capabilities and Financial Stability**

Describe the respondent's organization, management, history and financial stability.

3. **References**

Respondents should include a list of clients, organizations or institutions that can be used as references, paying particular attention to the eligibility requirement to have experience with at least three public health laboratories. Selected references may be contacted to determine the quality of work performed, competency of personnel assigned to the project, vendor responsiveness, etc. The results of the reference checks will be provided to the evaluation team and may be used in scoring the written proposal.

These references should be capable of verifying information supplied by the respondent in their proposal i.e. features or functions called out in this RFP. The data required for each reference includes:

- Company Name
- Address
- Contact person name, e-mail, address, phone number
- LIS Products being used
- Date of Implementation
- LIS Version Installed

4. **Examples of implementations within a laboratory setting**

Respondents should include a description of their relevant experience implementing and supporting LIS or working in a laboratory setting. Be specific and identify products and dates implemented. Also include information regarding laboratory departments using the provider's LIS, number of staff using the LIS, and the test types managed by the system. Please draw attention to public health laboratories worked with and multiple languages supported.

5. **Staff Qualifications**

The respondent must provide a project team organizational chart, followed by resumes of key personnel that will be assigned to the system implementation and training effort for the Georgia Phase 1 implementation. Each key personnel must be an employee of the respondent or be identified as a subcontractor. Include roles, responsibilities and estimated time allocated for each key personnel.

6. **TECHNICAL REQUIREMENTS**

Instructions: Respondents must provide a point-by-point response to requirements specified in this section of the RFP. This will require responding to more "general" and "open-ended" questions and requests for information as well as the more specific requirements found in the tables. Responses to

these Technical Requirements must be in the same sequence and numbered as they appear in this RFP.

Tables are divided into CORE REQUIREMENTS and SECONDARY REQUIREMENTS. Core requirements are absolute requirements for a LIS system selected for Phase 1. The secondary requirements represent preferences for a LIS application.

For CORE REQUIREMENTS and SECONDARY REQUIREMENTS found in the tables; indicate if your LIS "Meets", "Does Not Meet", "Requires Modification" or an "Alternative is Suggested". If the LIS "requires modification" or "alternative suggested" is selected; please add notes and further information into the table.

Note: As an option, you may respond by using the form fields built into this document (you must protect the form in the form toolbar to activate/inactivate fields)

7. Optimal Infrastructure

Please define the following in relation to the proposed LIS:

a. Minimum facility infrastructure requirements needed to support proposed LIS (from a physical as well as technical perspective)

b. Description of all additional software components (3rd party) needed in order to get a complete system as described in the technical and laboratory requirement sections of this RFP.

c. Cost for purchase, support and maintenance of these 3rd party items must be included in the cost breakdown sheet in Section 8.

d. Description/specifications of all recommended hardware i.e. workstations, printers, barcode printers, barcode readers, data backup devices needed in order to implement a complete system, as described in the technical and laboratory requirement sections of this RFP.

e. Description of minimum and optimum requirements for internet connectivity. It can be assumed that Phase 1 labs will be wired for connectivity. But as the internet access may not always be reliable, proposals must address how the LIS would be serviced, supported and maintained if internet access is not available/lab is not online.

8. Application

Web applications are preferred. Applications should be written in current programming languages screens with the flexibility for expansion and updating. Flexibility for updating and expansion are extremely important and will be a major consideration in the choice of the application.

a. What programming language(s) is the application software written in? If multiple languages are utilized, please describe the functions written in each.

	Select "Meets", "Does Not Meet", "Requires Modification" or "Alternative suggested". If the latter two are selected, please provide notes and/or further information.		**Notes and further Information**
	CORE Requirements		
a)	The official language in use in the Georgia laboratories is Georgian. Therefore, application screens, documentation and training materials must be presented in Georgian and English	Choose an item.	

b)	This LIS application should be considered a laboratory-oriented, sample-centric application as opposed to a patient-centric, patient management application.	Choose an item.	
	Secondary Requirements		
c)	Application should be designed to run in a Windows-based environment on PC's running MS Windows	Choose an item.	

9. System Database

The LIS system database will reside centrally in a private cloud or at the Georgia NCDC and possibly with local server in the laboratory for backup or continuation of operations. In response to this RFP, the respondent should recommend specifications for the database servers to handle the expected workload and throughput. These specifications should include the number of processors, speed, storage size and method, and backup recommendations.

Select "Meets", "Does Not Meet", "Requires Modification" or Alternative suggested. If the latter two are selected, please provide notes and/or further information.			**Notes and further Information**
	CORE Requirements		
a)	The type of database employed by the application needs to be a modern, relational database, widely supported by current technology	Choose an item.	
b)	If a commercial database is required, MS-SQL Server is preferable	Choose an item.	
	Secondary Requirements		
c)	System to retain 3 years of records without performance degradation.	Choose an item.	

10. System Logs

The System should contain logging capabilities as described below.

Select "Meets", "Does Not Meet", "Requires Modification" or Alternative suggested. If the latter two are selected, please provide notes and/or further information.			**Notes and further Information**
	CORE Requirements		
a)	System audit functionality should be maintainable (data points to capture) by the Lab system administrator or a supervisor via the application.	Choose an item.	
b)	System to allow authorized users to view or print audit logs using role based security.	Choose an item.	

11. System Security, Data Backup and Confidentiality of Data

i. The LIS must provide role-based data security. Access to data for all purposes must be controlled by roles. Please describe the different levels of role based access in the proposed system.

ii. The LIS should have the capability to perform routine backups of the data in the system. The LIS must have the ability to do both manual and scheduled data backups. The data backups must be done to a storage media that can be stored off-site and should also provide the ability to do backups to remote connected devices as well, for example a Network Attached Storage (NAS) architecture in the future. The system must provide data restore and recovery capabilities as well. Describe your plans for backing up data.

iii. Describe the access your company and each of your partner companies will have to patient information stored in the LIS database and any controls that are available to limit access to patient data.

iv. Describe any software that will be utilized that provides access to patient data.

v. Does your company typically sign non-disclosure or confidentiality agreements with your clients?

	Select "Meets", "Does Not Meet", "Requires Modification" or Alternative suggested. If the latter two are selected, please provide notes and/or further information.		**Notes and further Information**
	CORE Requirements		
a)	Unique ID and password sign-in for user authentication.	Choose an item.	
b)	Role-based security, providing appropriate user access to system functions and data.	Choose an item.	
c)	System data backup and recovery processes should have minimal impact on system availability.	Choose an item.	
	Secondary Requirements		
d)	Ability to add new, modify and delete roles to the security model by laboratory's LIS system administrator.	Choose an item.	
e)	System security levels to provide the ability to allow/disallow access to specific areas such as screens, windows, or logical data groupings by user role.	Choose an item.	

12. Data Exchange / System Interface

There are a number of existing information systems and databases operating or under development in Georgia. Proposed LIS must be able to interoperate with other MoH systems in the future, and although not a phase one requirement, the successful respondent's LIS will be able to capture and transmit data to a myriad of different applications and databases. Some systems currently in place in Georgia include:

- EIDSS surveillance system

Proposed

- Sharing of laboratory data with a central laboratory data repository location at MoH
- Data visualization/dashboards to enable viewing of laboratory data and key performance indicators.

- Electronic test order from remote clinic/field specimen collected or other facility and result reported transmitted back from LIS (eTOR)

Respondents should outline their proposed method of bi-directional data transmission and interoperability.

One of the major purposes of this project is to collect laboratory data in a timely fashion to facilitate allocation of resources, thus, data produced in the laboratory must be made available to the Georgia NCDC or other organizations as may be required. The LIS should, at a minimum, be able to store this information and easily export the data in a standardized electronic format for use. The format will be defined at a later date by the Georgia NCDC. The primary data to be monitored and aggregated are:

- summary workload and findings (by test)
- de-identified results data
- inventory (commodities)

Respondents should identify the capability and process of their system to store, collate and transmit summary management report data to the Georgia MoH. If the vendor currently has tools to perform this analysis without having all of the line-item test data in one database they should describe the functionality.

Select "Meets", "Does Not Meet", "Requires Modification" or Alternative suggested. If the latter two are selected, please provide notes and/or further information.			**Notes and further Information**
	Secondary Requirements		
a)	The system provides authorized users ability to extract data in a form that is used by a variety of commonly available analysis tools.	Choose an item.	
b)	The system to handle batch imports or data loads from standard data formats.	Choose an item.	
c)	System to utilize HL7 v2 or FHIR standard messages for interfacing to other systems.	Choose an item.	
	System to utilize web service components for data interfaces.		

13. System documentation

The system needs to be appropriately documented, come with a full set of documentation, and include any specifications pertinent to the installation of the system.
Include any costs associated with providing this documentation in the LIS Application Cost Sheet found in Section 8.

Select "Meets", "Does Not Meet", "Requires Modification" or Alternative suggested. If the latter two are selected, please provide notes and/or further information.			**Notes and further Information**
	CORE Requirements		

a)	Vendor to deliver system documentation at the conclusion of initial installation and deployment of the system, including any specifications pertinent to the Georgia LIS. The documentation should be presented as hard copy reference materials, and/or electronic format and include the following:	Choose an item.	
b)	**Installation and administration guide:** The installation guide shall be detailed enough to provide system administrators with information necessary to install and bring the application live in a production environment. The documentation shall list all utilities and tools necessary for the proper administration of the LIS. These tools shall cover management and administration of the LIS database, the user interface, and any auxiliary programs integrated into the delivered LIS.	Choose an item.	
c)	**End user guide:** Laboratory User documentation shall be sufficient and detailed enough to allow different levels of lab users to perform their functions without having to rely on external support.	Choose an item.	
d)	**Super User guide:** an overview of system and complete user documentation regarding Use of all applications, adding or modifying test procedures, adding or modifying testing controls, adding or modifying new data elements to the database for collection at test order entry, result data entry and for reporting, adding or modifying testing alerts and result calculations, adding or modifying reflex testing rules, adding or modifying report formats, adding or modifying a system rule, and developing electronic file formats for import or export.	Choose an item.	
	Secondary Requirements		
e)	**Operations and troubleshooting guide:** this documentation shall include information on troubleshooting and support escalation procedures and response times. Ideally, the respondent would be able to provide a centrally managed, web based knowledge database that users can access to get the latest	Choose an item.	

	information on troubleshooting, support, bugs, updates, etc.		
f)	Contractor to provide system data dictionary and data model. To include hard copy reference materials and/or other electronic format.	Choose an item.	

14. Training requirements

Two levels of training are anticipated, one geared towards LIS Administrators and Super Users, and one geared towards end users. Respondents should propose a training program necessary to provide these trainings as part of this RFP and respond to the following specific requirements:

a. Two or more individuals per site selected as "Super Users" will be trained on the technical aspects of the software and the overall laboratory hardware and software configuration, so that typical or simple technical problems can be managed on-site without having to call the vendors customer support group. These super users should also be trained to perform simple changes to the software such as adding a new test, assigning passwords, etc. Describe how this training would be conducted; include number and length of training sessions, number of people in each session, and description of materials provided and at what point during the installation this will be done.

b. Respondent must provide initial training and post-live supportive supervision for end users on-site in conjunction with system installations. The basic end user training for **each** site should be a minimum of one week and supportive supervision two weeks. Describe how this training would be conducted; include number and length of training sessions, number of people in each session, description of materials provided and at what point phase during the installation this will be done.

c. Respondents should propose how additional or new users of the system can be trained on the application software (Post Installation) and cost. Costs associated with each type of training should be shown on the cost sheet in Section 8. Proposals that identify a local partner to provide aspects of support are preferred.

Select "Meets", "Does Not Meet", "Requires Modification" or Alternative suggested. If the latter two are selected, please provide notes and/or further information.			**Notes and further Information**
	CORE Requirements		
a)	One or more individuals per site selected as "Super Users" must be trained on the technical and administrative aspects of the software as well as the laboratory hardware and software configuration	Choose an item.	
b)	Minimum one week basic end user training must be provided for each site	Choose an item.	
c)	Minimum two weeks post-live supportive supervision must be provided for each site	Choose an item.	

15. GAP Analysis, Software Template, and Customization/Configuration

i. The respondent may perform a GAP analysis prior to implementation to clearly identify changes to the core system (data elements, and reporting requirements). Describe your process and explain if this is part of your normal implementation or is provided at additional cost. If an additional cost, please provide details in Section 8.

ii. Does your company expect to utilize a template or specific version of the LIS software for this project? If yes, describe in detail the information and screens available in this template.

iii. To what level can the LIS be customized by trained laboratory administrators and super users? At what point must the customization be done by LIS programmers?

Select "Meets", "Does Not Meet", "Requires Modification" or Alternative suggested. If the latter two are selected, please provide notes and/or further information.			Notes and further Information
	Secondary Requirements		
a)	A GAP analysis of the LIS software will be performed prior to implementation	Choose an item.	
b)	Will utilize a template or specific version of the LIS software for this project	Choose an item.	
c)	System allows users to customize and maintain (add, modify, delete) forms, screens and system components used for test order entry, result entry and result reporting.	Choose an item.	

16. Software Support

For the purposes of the RFP, software support will refer to the helpdesk services supplied by the respondent for users of the software following initial training and installation of the software in the Georgia laboratories. Computer and network hardware maintenance and support will be provided by a local company or companies selected by APHL, Georgia NCDC, and CDC-Georgia. The selected vendor will be expected to work closely with this local hardware provider to support the operation of the LIS.

i. Provide specific details about application support.

ii. The respondent must define the type and level of technical support and maintenance performed by:
   - personnel on-site
   - local support or partner company
   - remotely/via web
   - staff travel from an office outside of Georgia.

iii. Specific costs associated with this support must be supplied and if several alternative types of support are bid, specific costs associated with each type of support must be supplied in Section 8. Descriptions of any alternative types of support can be described here:

iv. Does your technical support and maintenance plan include remote access, so that changes or fixes can be made to the system? Describe any software to be utilized for these purposes.

v. Expected response times, resolution times, priority levels and a description of how the respondent ensures timely and competent support must be described.

Select "Meets", "Does Not Meet", "Requires Modification" or Alternative suggested. If the latter two are selected, please provide notes and/or further information.			Notes and further Information
	CORE Requirements		
a)	Vendor to provide ongoing technical support for system administrators and super users.	Choose an item.	

b)	Vendor to provide technical support Monday thru Friday, 8:00 to 18:00 Georgia time.	Choose an item.	
c)	Vendor to prioritize technical support calls and address them in priority order. Minimal response and resolution times should be associated with type of priority.	Choose an item.	

17. System maintenance/updates

For the purposes of the RFP, software maintenance will refer to application updates and patches to the software following official installation in the Georgia laboratories.

i. Provide specific details of how software will be maintained in Georgia throughout its lifetime; how patches, updates or enhancements will be installed.
ii. Specific costs associated with maintenance and support of the software after **year one**. These costs should be shown separately in annual amounts on the LIS Application Cost Sheet in Section 8.
iii. Explain software maintenance and support cost i.e. what is included in the yearly software maintenance and support cost and what is not included and requires additional cost. Identify the additional items and cost for each.
iv. Describe your historical release cycle and plans for the future and how system updates are performed.
v. Describe how system updates are performed, by whom.

Select "Meets", "Does Not Meet", "Requires Modification" or Alternative suggested. If the latter two are selected, please provide notes and/or further information.			**Notes and further Information**
	CORE Requirements		
a)	System upgrade procedures should have minimal impact on system availability.	Choose an item.	
b)	Vendor to provide version control of the system and periodic system updates and maintenance releases to update technology.	Choose an item.	

18. LABORATORY BUSINESS REQUIREMENTS

Instructions: Respondents must provide a point-by-point response to requirements specified in this section of the RFP. This will require responding to more "general" and "open-ended" questions and requests for information as well as the more specific requirements found in the tables. Responses to these Business Requirements must be in the same sequence and numbered as they appear in this RFP.

Tables are divided into CORE REQUIREMENTS and SECONDARY REQUIREMENTS. Core requirements are absolute requirements for a LIS system selected for the Georgia laboratories. The secondary requirements represent preferences for a LIS application.

For CORE REQUIREMENTS and SECONDARY REQUIREMENTS found in the tables; please indicate if your LIS "Meets", "Does Not Meet", "Requires Modification" or an "Alternative is Suggested". If the LIS

"Requires Modification" or "Alternative Suggested" is selected; please add notes and further information into the table.

Note: As an option, you may respond by using the form fields built into this document (you must protect the form in the form toolbar to activate/inactivate fields)

The laboratory requirements in this section are meant to be a guide for respondents in responding to this RFP and to ensure that respondents understand the data that needs to be collected and communicated within the Georgia laboratories. Once an application has been selected, specific data, specific screen design and modification of the software to meet logistical laboratory requirements will be negotiated.

19. Laboratory throughput and hours of operation

Phase 1 Following are the expected number of tests performed on an annual basis by each laboratory

LABORATORY	STATISTICS	STAFFING
NCDC Georgia		TBD

Note: While the labs do provide some test services on a 24/7 schedule, most services are provided within a regular working day from 8:00am – 5:00pm.

20. Specimen Registration and Processing

The description of the system which follows is a general example of the sample flow and the requirements of a LIS in a typical laboratory registration. It is provided, to help you complete the table of requirements in this section.

Typically, laboratory test request orders are initiated by a clinician who fills out a test request. While the data required in the form is usually the same, the format of request forms used within the health care system may vary from place to place. Samples are then transferred/referred to the NCDC. The physical orientation of the facility and the logistics of the laboratory often determine where the sample collection takes place. In addition, some samples are collected in the field as part of an event investigation and brought to the laboratory. ***Regardless of where the sample is taken, the sample request information must be logged into the LIS, along with required demographic information, and matched with the patient sample.***

A unique specimen identifier for each sample (or sample number) that can be placed on the sample and the sample request form should be generated through the LIS. Whether aliquots from the same sample have their own additional unique identifier is open to negotiation. The form and type of identifier is open to negotiation, the use of bar code printers and scanners to produce and read sample data is the preferred method of utilizing these data. You are welcome to provide any comments to this information:

Select "Meets", "Does Not Meet", "Requires Modification" or Alternative suggested. If the latter two are selected, please provide notes and/or further information.			**Notes and further Information**
	CORE Requirements		

a)	System should allow for rejection of specimen right at specimen receipt following registration. This will complete the testing cycle for this specimen.	Choose an item.	
b)	System supports the ability to perform a quick entry (not all patient demographics are entered) so that a specimen ID is assigned, tests are assigned, barcode labels printed and testing can begin. Full demographics can be entered at any time before reporting is done	Choose an item.	
c)	System supports complete order entry and assigns a unique specimen identifier with a bar coded label to each sample	Choose an item.	
d)	The system should maintain a complete audit trail of order process. This audit trail MUST be visibly accessible to an authorized LIS user Auditing should include: • Status of each change that an order undergoes • Date and time of event change • ID of person who changed the order	Choose an item.	
e)	The system should have the ability to search for previous patient information to link current request with previous demographics; when a returning patient is found, system must be able to pre-populate demographic information with the ability to edit and save.	Choose an item.	
f)	There are sample submission or requisition forms used by hospitals and health services clinicians to request laboratory analysis in the Georgia public health laboratories. The following patient and specimen data fields should be expected in this standardized form and required in a LIS: • Specimen Identification Number – a unique sample identifier which should be generated in the laboratory at the time of sample receipt and used to identify a specific sample. LIS should be able to capture all identifier used by B/BTKL-PPs and generate/assign a new identifier if needed. • Date Received/Time Received – Date and time the sample was received by the laboratory • Patient Name/ID Number – Name of patient or patient identifier if the sample is collected without name. • Patient Sex – Sex of the patient. • Patient's Date of Birth (Age) – Patients birth date should also show calculation of age. If a birth date is supplied the age should be calculated. Also, if DOB is not known, the age of the patient is used to calculate the DOB. It	Choose an item.	

	is logged with the sample and with the patient information. • Patient address 1: street address, house number, RT/RW, village • Patient address 2: city and district • Patient address 3: Province • Phone number – reachable home phone number • Mobile number • Postal code: postal code of patient • Ward – Ward (if sample was collected in a hospital) • Medical Registration Number – Chart number of hospital patient • National ID Number – National Identifier • District – Name of district where the sample was collected • Region – Name of region where the sample was collected • Name of Hospital – Hospital or clinic where the sample was collected • External Lab Number – If the sample is received from another location there is the need to track the ID supplied by the external source. • Collection Date – Date sample was collected • Collection Time – Time sample was collected • Sample Type – Type of sample presented for analysis • Receipt Number – Receipt number for patients who have paid for the analysis • Amount Paid or Receipt Number – The amount paid by the patient for the test • Investigation Required – Tests requested • Requested by – Name of person requesting test • Date requested – Date the test was requested • Comments about sample(s) • Clinical history and provisional diagnosis • Priority—Routine or Urgent		
g)	The capability for the electronic referral of specimens to external laboratories if the testing is not performed at their laboratory and the capability for electronic receipt of reported data. The system must be able to maintain the record of this referral and allow for the entering of result data when received from referral laboratory.	Choose an item.	
h)	LIS systems installed in laboratories which receive referrals from other laboratories should have the capability of the electronic receipt of referred specimens and the capability of electronic reporting	Choose an item.	

	of sample results along with the requisite tracking mechanisms to ensure that both the samples and the results get to the appropriate locations efficiently.		
i)	The ability for an authorized submitter to look up patient results through a mobile device or PC	Choose an item.	
j)	The ability for the LIS to remotely order tests and report results electronically. The system should either have or be extensible enough to accommodate this feature.	Choose an item.	
	Secondary Requirements		
k)	System to allow the ability to prioritize testing of a specimen. Priorities should be user definable and modifiable	Choose an item.	
l)	The system should support duplicate order checking during order processing that: • Detects duplicates of currently active orders • Detects duplicates of inactive or already performed orders	Choose an item.	

21. Specimen INVENTORY OR STORAGE OR TRACKING

The System should provide for specimen inventory or storage tracking.

Select "Meets", "Does Not Meet", "Requires Modification" or Alternative suggested. If the latter two are selected, please provide notes and/or further information.			**Notes and further Information**
	Secondary Requirements		
a)	System to provide the ability to track samples: • Within a laboratory, i.e. workstations, refrigerators, incubators, etc. • Between labs or lab sections and into specimen racks or storage containers • To storage locations via rack or container ID. • Track when a specimen is removed from storage. • Track specimen to destruction.	Choose an item.	
b)	System to provide the ability to create user-definable bar code labels and parameters for storage locations, storage containers and specimen racks.	Choose an item.	

22. Testing and Result Entry

Every effort should be made to decrease the amount of data entry required for analysts. Data that have been previously entered into the LIS should not have to be re-keyed for any reason. Data required by analytical instrumentation to ensure sample identification and to meet QA/QC requirements should be uploaded from the instrument if the instrumentation supports electronic transfer of data. In addition, results of analyses should be subsequently downloaded into the LIS along

with identifying information to link test results with the correct sample. When automatic uploading and/or downloading of data are not possible, steps should be introduced to simplify and automate the transmission of data into or from the LIS application. The laboratory instrumentation to be interfaced (if possible) is provided in Section 6.9.

Select "Meets", "Does Not Meet", "Requires Modification" or Alternative suggested. If the latter two are selected, please provide notes and/or further information.			**Notes and further Information**
	CORE Requirements		
a)	System should allow for rejection at any time during the testing process	Choose an item.	
b)	The ability to cancel specific tests and reject specimens must be allowed. A reason for a canceled test or rejected specimen should be able to be entered and the reason reported back to the submitter.	Choose an item.	
c)	The ability to repeat a test on a specimen and have it appear on the next work list	Choose an item.	
d)	Access to results data shall be based on user roles and privileges	Choose an item.	
e)	System should automatically capture workload and test statistics	Choose an item.	
f)	The system should provide for a supervisor verification step prior to releasing patient results.	Choose an item.	
g)	System must also provide for manual result entry. This will accept an accession (manually or via bar code) and allow the analyst to enter results.	Choose an item.	
h)	System should provide user-defined reflex testing protocols, test calculations and interpretive reporting.	Choose an item.	
i)	System should be able to produce a printable "work list" for each test area. This will identify the specimens ordered and ready for testing in this area (including any repeat samples)	Choose an item.	
j)	System must be able to allow for specimens to be referred to a secondary laboratory for further testing if initial test results (or testing algorithm) require further confirmation or follow up testing. The system must be able to maintain the record of this referral and allow for the entering of result data when received from referral laboratory. Examples of referred testing is Mycobacterium Tuberculosis (TB) as B/BTKL-PPs refer specimens from laboratories for confirmation/diagnostic testing.	Choose an item.	

23. Reports

a. There are existing patient result report formats and summary or aggregate reports utilized by the laboratories at the Phase 1 sites. These reports must be generated by the LIS, so should be included in the costs submitted.

b. List the reports that can be generated by the LIS with the initial system and detail the mechanism for creating the existing NCDC patient and aggregate reports.

c. Will future reports be created by the LIS provider or laboratory personnel? If both options available, please explain the difference in reports.

d. Provide the costs associated with creating new reports and note any third party software that is utilized for the generation of reports.

Select "Meets", "Does Not Meet", "Requires Modification" or Alternative suggested. If the latter two are selected, please provide notes and/or further information.			**Notes and further Information**
	CORE Requirements		
a)	Once the requested test has been completed and result data entered into the LIS, a printed report of analysis should be produced for delivery to the clinician and client. In addition, data required to reproduce the report in the future must be stored within the application.	Choose an item.	
b)	The system must produce pending result reports, which include: • If the results have not been verified and accepted • If the tests have been ordered but not performed • If a test procedure has gone beyond the normal turnaround time	Choose an item.	
c)	The system must produce reports for positive test results and de-identified aggregate health data for any given time period	Choose an item.	
d)	The system must produce workload statistics reports. This should be a summary list for selected time periods (days, hours, etc.), submitters, tests, laboratory sections and instruments. This includes, but is not limited to the following reports: • Tests performed • Rejected test results • QC samples tested • Turnaround time reports	Choose an item.	
e)	The ability to print interim reports that contain preliminary result findings.	Choose an item.	
f)	System should have the ability to produce reports in either an on-going, real-time process or printed on-demand in batches.	Choose an item.	
	Secondary Requirements		
g)	When multiple tests are ordered on the same specimen, the LIS should support the option to do the following:	Choose an item.	

	• Issue an interim report with available results and an indication that a test is pending and will follow • Interim reports would be issued until all tests are complete for that specimen and each interim report will contain all completed test results to date, along with indication of any tests that are pending • When all tests are completed, a final report will be issued which contains all completed test results • Hold all test results for a specimen until all work is complete and a final report issued		
h)	System should support transmitting reports and results to other systems.	Choose an item.	
i)	The system should provide data mining techniques and reports selected by: • Date range • Test procedure • Submitter • Other criteria identified by the laboratories	Choose an item.	

24. Quality Assurance/Quality Control

The LIS application software bid must have a method for the implementation of a comprehensive laboratory quality assurance program utilizing standard quality control measures and proficiency samples. Describe the QA/QC capabilities and functions included in the LIS and how QC parameters and features are defined.

Select "Meets", "Does Not Meet", "Requires Modification" or Alternative suggested. If the latter two are selected, please provide notes and/or further information.			**Notes and further Information**
	CORE Requirements		
a)	System must maintain quality control checking for instruments and manual input.	Choose an item.	
b)	The QC parameters and features must be user definable by laboratory, and test type/method.	Choose an item.	
c)	QC methodology must be capable of linking any specific sample with the quality control measures employed by the analysis and recording within the software all aspects of the analytical process, including analysts.	Choose an item.	
d)	System must maintain a complete audit trail of the result process including: • Date and time of event change and initial result entry • Record each step that occurred in the processing of a test procedure	Choose an item.	

	• User who performed the step • Quality control		
e)	System should produce cumulative weekly and monthly quality control reports.	Choose an item.	
f)	System must have ability to flag samples as external quality control samples or proficiency samples; these results should not be included in aggregate reports (should not skew test statistics)	Choose an item.	

25. Laboratory Equipment and Personnel Data Inventory

The LIS should support the management of laboratory supplies inventory, equipment inventory, and personnel data. Possible data elements to be captured in these areas are provided in the table below. These data elements may change and the LIS must be flexible enough to allow for changes. Describe the capability of your LIS to handle these data and the steps to be taken to meet these requirements.

Select "Meets", "Does Not Meet", "Requires Modification" or Alternative suggested. If the latter two are selected, please provide notes and/or further information.			**Notes and further Information**
	Secondary Requirements		
a)	System should have ability to manage laboratory inventory. Below are data elements that may be tracked as part of the inventory management at the laboratories. • Date • Shift • Commodity • Unit of issue • Beginning Balance • Quantity Received • Origin • Batch No. • Expiration Date • No. of Tests Done • Quantity used • Losses/Adjustments • Ending Balance • Remarks • Name of person making entry	Choose an item.	
b)	System should have ability to manage equipment inventory. Below are possible data elements that may be tracked for equipment. • Equipment Name • Department • Manufacturer	Choose an item.	

	• Model • Serial number • Date Received • Date Inspected • Calibration Date • Dates or interval of required calibration or maintenance • Date of Next Inspection • Date of Next Calibration • Warranty End Date • Status		
c)	System should have ability to manage personnel inventory. The following are the initial data elements maintained for personnel: • Name • Location/Facility • Education Level • Specialty • Department • General Notes and Training record • Start Date • End Date	Choose an item.	

26. Tests

While the purpose and objective of this LIS implementation within the Georgia laboratories is to ensure that the laboratories can provide timely and accurate services and information to support public health infectious disease testing, it is recognized that these same laboratories must also respond to service and information requests for other testing services. Consequently, the proposed LIS application should have the capability of capturing and reporting data for the range of clinical diagnostic tests associated with diseases of public health and the possibility to include water and environmental testing. The following list represents potential tests that could be analyzed in Phase 1 and should be included in any LIS application. Not all laboratories will have the capability of performing all these tests and there may be other tests performed that are not on this list. This list, however, represents the majority of tests performed in the Georgia laboratories. Describe the capability of your LIS to handle these tests and your plan for implementation.

Test name/method	Tests in LIS (check Yes if system meets)	
Influenza		
Influenza real time RT-PCR	☐ Yes	☐ No
Influenza virus isolation on MDCK cells	☐ Yes	☐ No
Influenza subtyping by HIA	☐ Yes	☐ No
Sanger sequence method for Influenza virus Neuraminidase and Hemaglutinin genes	☐ Yes	☐ No

Respiratory viruses detection by singleplex real time PCR	☐ Yes	☐ No
Respiratory viruses detection by multiplex real time PCR	☐ Yes	☐ No
Mers Cov real time RT-PCR	☐ Yes	☐ No
SARS-CoV-2 real time RT-PCR	☐ Yes	☐ No

Test name/method	Tests in LIS (check Yes if system meets)	
Bacteriology		
Microbiology investigation of stool sample	☐ Yes	☐ No
Microbiology investigation of urine sample	☐ Yes	☐ No
Microbiology investigation of Bronchoalveolar lavage and sputum samples	☐ Yes	☐ No
Microbiology investigation of samples from low respiratory tract	☐ Yes	☐ No
Microbiology investigation of different swab samples	☐ Yes	☐ No
Microbiology investigation of cerebrospinal fluid	☐ Yes	☐ No
Microbiology investigation of blood sample	☐ Yes	☐ No

Test name/method	Tests in LIS (check Yes if system meets)	
Parasitology		
Cultivation of human boold sample for isolation of species for Francisella tularensis, Yersinia pestis, Bacillus anthracis and Brucella	☐ Yes	☐ No
Bacillus anthracis -cultivation form human, enviromental and contaminated samples	☐ Yes	☐ No
Brucella species: Rose Bengal strips for detection sera antiboys- health care/veterinary	☐ Yes	☐ No
Brucella speaces : culture from human and animal samples	☐ Yes	☐ No
Francisella tularensis cultivation from human sample	☐ Yes	☐ No
Yersinia pestis: cultivation from human sample	☐ Yes	☐ No
collceting exoparasites at Lugar center from rodent's carrions and nest	☐ Yes	☐ No
preparation of exoparasites samples for investigation at Lugar center	☐ Yes	☐ No
preparation of specimen from rodent samples at Lugar center	☐ Yes	☐ No
preparation of specimen from soil and hay sample	☐ Yes	☐ No

aglutination method for detecting anti phseudotuberculosis antibodies in human sera	☐ Yes	☐ No
aglutination method for detecting anti Yersinia enterocolitica antibodies in human sera	☐ Yes	☐ No
Botulism	☐ Yes	☐ No

Test name/method	Tests in LIS (check Yes if system meets)	
Polio		
PV and NPEV isolation and identification	☐ Yes	☐ No
real time RT-PCR for Polio	☐ Yes	☐ No

Test name/method	Tests in LIS (check Yes if system meets)	
Molecular		
B. anthracis DNA detection in clinical/environmental sample, or culture confirmation - Real Time PCR, Target 2, 3	☐ Yes	☐ No
Y. pestis, DNA detection in clinical/environmental sample, culture confirmation, Real Time PCR, Target 1, 2	☐ Yes	☐ No
Y. pestis, DNA detection in clinical/environmental sample, culture confirmation, Real Time PCR, Chromosomal, pMT,pCD,PCP	☐ Yes	☐ No
/Hanta Dob./Pum. RNA detection in clinical/environmental sample, Real Time PCR,	☐ Yes	☐ No
Brucella spp. DNA detection in clinical/environmental sample, or culture confirmation - Real Time PCR, Target 1	☐ Yes	☐ No
F. tularensis DNA detection in clinical/environmental sample, or culture confirmation- Real Time PCR, Target 1,	☐ Yes	☐ No
CCHF and Ebola/Marburg viruses RNA detection in clinical/environmental sample- Real Time PCR	☐ Yes	☐ No
Orthopoxvirus , DNA detection in clinical/environmental sample- Real Time PCR	☐ Yes	☐ No
Parapoxvirus, DNA detection in clinical/environmental sample- Real Time PCR	☐ Yes	☐ No
HCVReal-TM Qual/ HCV Qualitative, RNA detection inclinical sample (Qualitative detection), Real Time PCR, HCVReal-TM Qual	☐ Yes	☐ No
HCV Genotipe, RNA detection inclinical sample (Genotipe Identification), Real Time PCR, HCVReal-TM Genotype	☐ Yes	☐ No

E. coli toxin gene detection in clinical sample, culture confirmation, Conventional PCR, STEC multiplex	☐ Yes	☐ No
E. coli EAEC detection assay in clinical sample, culture confirmation, Conventional PCR, STEC multiplex	☐ Yes	☐ No
E. coli O104 E. coli confirmation assay in clinical sample, culture confirmation, Conventional PCR, STEC multiplex	☐ Yes	☐ No
Leishmania, species specific DNA detection in clinical sample, Conventional PCR, Leishm.donovani/infantum	☐ Yes	☐ No
Rabies, RNA detection from clinical sample (saliva), Conventional PCR, RT-PCR,nested PCR,Sanger sequencing	☐ Yes	☐ No
Malaria, DNA detection in clinical sample, Real Time PCR, P. falciparum, P. vivax, P. malariae	☐ Yes	☐ No
Rickettsia spp. DNA detection in environmental sample, Real Time PCR, Rick17Kb	☐ Yes	☐ No
Rickettsia raoultii, DNA detection in environmental sample, Real Time PCR	☐ Yes	☐ No
Rickettsia slovaca, DNA detection in environmental sample, Real Time PCR	☐ Yes	☐ No
Rickettsia aeschlimannii, DNA detection in environmental sample, Real Time PCR	☐ Yes	☐ No
Borrelia burgdorferi, DNA detection in environmental sample, Real Time PCR	☐ Yes	☐ No
Ehrlichia chaffenses, DNA detection in environmental sample, Real Time PCR	☐ Yes	☐ No
Dengue virus detection in clinical samples, Real-Time PCR	☐ Yes	☐ No
Chikungunia virus detection in clinical samples, Real-Time PCR	☐ Yes	☐ No
Zika virus detection in clinical samples, Real-Time pCR	☐ Yes	☐ No
West Nile virud detection in clinical sample, Real-Time PCR	☐ Yes	☐ No

	Test name/method	Tests in LIS (check Yes if system meets)	
	Serology		
1	Detection of antibodies against Hepetities A by ELISA	☐ Yes	☐ No
2	Detection of antibodies against Hepetities E by ELISA	☐ Yes	☐ No
3	Norovirus Ag qualitative identification in human stool sample by ELISA	☐ Yes	☐ No
4	Rotavirus Ag qualitative identification in human stool sample by ELISA	☐ Yes	☐ No

5	Adenovirus Ag qualitative identification in human stool sample by ELISA	☐ Yes	☐ No
6	Quantitative and qualitative detection of IgG antibodies against Francisella tularensis by ELISA	☐ Yes	☐ No
7	Quantitative and qualitative detection of IgM antibodies against Francisella tularensis by ELISA	☐ Yes	☐ No
8	Detection of antibodies against F. tularensis by MAT	☐ Yes	☐ No
9	Quantitative and qualitative detection of IgM antobodies against Brucella by ELISA	☐ Yes	☐ No
10	Quantitative and qualitative detection of IgG antobodies against Brucella by ELISA	☐ Yes	☐ No
11	detection of IgM antibodies against Rickettsia (Typhus group) by ELISA	☐ Yes	☐ No
12	detection of IgG antibodies against Rickettsia (Typhus group) by ELISA	☐ Yes	☐ No
13	detection of IgM antibodies against Rickettsia (spotted fever group) by ELISA	☐ Yes	☐ No
14	detection of IgG antibodies against Rickettsia (spotted fever group) by ELISA	☐ Yes	☐ No
15	detection of IgG antibodies against Coxiella burnetii (Phase I) by ELISA	☐ Yes	☐ No
16	detection of IgM antibodies against Coxiella burnetii (Phase II) by ELISA	☐ Yes	☐ No
17	Quantitative and qualitative detection of IgM antibodies against Dengue virus by ELISA	☐ Yes	☐ No
18	Quantitative and qualitative detection of IgG antibodies against Dengue virus by ELISA	☐ Yes	☐ No
19	Quantitative and qualitative detection of IgG antibodies against Leptospira by ELISA	☐ Yes	☐ No
20	Quantitative and qualitative detection of IgM antibodies against Leptospira by ELISA	☐ Yes	☐ No
21	Qualitative determination of leishmania Ab	☐ Yes	☐ No
22	detection of IgG antibodies against Bartonella henselae/ Bartonella quintana by IFA	☐ Yes	☐ No
23	detection of IgM antibodies against Bartonella henselae/ Bartonella quintana by IFA	☐ Yes	☐ No
24	Qualitative detection of IgM antibodies against Bordetella pertussis by ELISA	☐ Yes	☐ No
25	Qualitative detection detection of IgG antibodies against Bordetella pertussis by ELISA	☐ Yes	☐ No
26	detection of IgM antibodies against Enterovirus by ELISA	☐ Yes	☐ No
27	detection of IgG antibodies against Enterovirus by ELISA	☐ Yes	☐ No
28	detection of IgG antibodies against Epstein-Barr virus capsid antigen by ELISA	☐ Yes	☐ No
29	detection of IgM antibodies against Epstein-Barr virus early antigen by ELISA	☐ Yes	☐ No

30	detection of IgM antibodies against Borrelia by ELISA	☐ Yes	☐ No
31	detection of IgG antibodies against Borrelia by ELISA	☐ Yes	☐ No
32	detection of IgM antibodies against Borrelia by immunoblotting	☐ Yes	☐ No
33	detection of IgG antibodies against Borrelia by immunoblotting	☐ Yes	☐ No
34	detection of IgM antibodies against Borrelia by IFT	☐ Yes	☐ No
35	detection of IgG antibodies against Borrelia by IFT	☐ Yes	☐ No
36	detection of IgM antibodies against Chikungunia by ELISA	☐ Yes	☐ No
37	detection of IgG antibodies against Chikungunia by ELISA	☐ Yes	☐ No
38	detection of IgM antibodies against West Nile Virus by ELISA	☐ Yes	☐ No
39	detection of IgG antibodies against West Nile Virus by ELISA	☐ Yes	☐ No
40	detection of IgM antibodies against Hanta virus by ELISA	☐ Yes	☐ No
41	detection of IgG antibodies against Hanta virus by ELISA	☐ Yes	☐ No
42	detection of IgM antibodies against Parvo virus (B19) by ELISA	☐ Yes	☐ No
43	detection of IgG antibodies against Parvo virus (B19) by ELISA	☐ Yes	☐ No
44	detection of IgM antibodies against Mumps virus by ELISA	☐ Yes	☐ No
45	detection of IgG antibodies against Mumps virus by ELISA	☐ Yes	☐ No
46	detection of IgM antibodies against Tick borne virus by ELISA	☐ Yes	☐ No
47	detection of IgG antibodies against Tick borne virus by ELISA	☐ Yes	☐ No
48	detection of IgM antibodies against Zika virus by ELISA	☐ Yes	☐ No
49	detection of IgG antibodies against Zika virus by ELISA	☐ Yes	☐ No
50	detection of IgM antibodies against Zika virus by IFT	☐ Yes	☐ No
51	detection of IgG antibodies against Zika virus by IFT	☐ Yes	☐ No
52	detection of IgM antibodies against Crimean-Congo Hemoragic Fever virus by ELISA	☐ Yes	☐ No
53	detection of IgG antibodies against Crimean-Congo Hemoragic Fever virus by ELISA	☐ Yes	☐ No
54	Detection of Hepatities B surface antigen (HBs Ag) by ELISA	☐ Yes	☐ No
55	Detection of Hepatities B surface antigen by ELISA	☐ Yes	☐ No
56	detection of IgM antibodies against Measles virus by ELISA	☐ Yes	☐ No

57	detection of IgG antibodies against Measles virus by ELISA	☐ Yes	☐ No
58	detection of IgM antibodies against Rubella virus by ELISA	☐ Yes	☐ No
59	detection of IgG antibodies against Rubella virus by ELISA	☐ Yes	☐ No
60	determination of Rubella virus avidity determination native antigens by ELISA	☐ Yes	☐ No
61	Detection of Hepatities B surface antigen (HBs Ag) by CMIA	☐ Yes	☐ No
62	Detection of Hepatities B surface antigen (HBs Ag Confirmatory) by CMIA	☐ Yes	☐ No
63	Detection of antibodies against HIV I/II by CMIA	☐ Yes	☐ No
64	Detection of Hepatities C core antigen (HCVcore Ag) by CMIA	☐ Yes	☐ No
65	Detection of antibodies against Hepatities B core antigen (HBc Ab) by CMIA	☐ Yes	☐ No
66	Detection of antibodies against T. Palidiumby CMIA	☐ Yes	☐ No
67	Detection of antibodies against Hepatities C (HCVAb) by CMIA	☐ Yes	☐ No
68	Detection of IgM antibodies against Varicella zoster virus	☐ Yes	☐ No
69	Detection of IgG antibodies against Varicella zoster virus	☐ Yes	☐ No
70	detection of IgM antobodies against Yellow Fever virus by IFT	☐ Yes	☐ No
71	detection of IgG antobodies against Yellow Fever virus by IFT	☐ Yes	☐ No
72	detection of IgA and IgG antobodies against SARS-CoV-2 by ELISA	☐ Yes	☐ No
73	detection of IgG antobodies against SARS-CoV-2 by CMIA	☐ Yes	☐ No
74	detection of antobodies (Ab) against SARS-CoV-2 by ECLIA	☐ Yes	☐ No

27. Equipment/instrumentation interfaces

The tables below provide the instrumentation available in each of the four Phase 1 laboratories. Each instrument listed should be interfaced to the LIS directly for uploading and downloading of data if possible. For LIS that are capable of interfacing with laboratory instrumentation, respondents should indicate the type and cost of interface devices that are required for the proposed LIS. Explain the cost for each new instrument interface and the cost for an instrument you have already interfaced.

a. Describe how you will interface each instrument and accept data (i.e. uni-directional, bi-directional).
b. List the instruments your system has been interfaced with.
c. Do you charge for support on each interface?

28. IMPLEMENTATION PLAN

Outline your implementation plan or project plan for the LIS installation, providing a list of activities, the roles and responsibilities of key individuals for each activity and a tentative timeline for the project.

29. **COST PROPOSAL & SYSTEM ACCEPTANCE**
30. **Submitting Quotes**

The LIS Application Cost Sheet is to be used by the respondents to provide details of all costs with submitted proposal. We request a detailed budget for Phase 1 and high level estimation for Phase 2 deployment. Vendors can assume that the in Phase 2 are similar to the in Phase 1. The summary cost sheet must be completed and signed by the authorized company representative in addition to any detailed price and descriptive information provided in the response. All costs of complying with the terms and conditions of this RFP must be shown on the LIS Application Cost Sheet. Any reductions to the costs which the respondent is offering as a part of its total proposal should be listed on LIS Application Cost Sheet, clearly labeled as reductions. Options

Options listed below are provided to vendors with the capability of supplying other hardware and software outside the scope of the LIS application software. A vendor may or may not choose to bid these items. APHL, in consultation with the Georgia NCDC and CDC-Georgia, has the option of choosing or not choosing any or all of the options.

31. **Barcode printers and scanners: A vendor may choose to supply bar code printers and scanners required to support the LIS application bid. Specific requirements and costs associated with this option will be negotiated as part of the contract negotiation with the selected vendor and do not need to be listed on the initial proposal cost**Page Break**LIS Application Cost Sheet**

Respondent Name:

Name of LIS Suggested:

ITEM	**TOTAL COST (in USD)**
Purchase	
Price – LIS License, Software Maintenance & Support for Year 1: *List modules included in the LIS product license. Indicate whether the licensing of the application software is by workstation (or concurrent user) or by installation. APHL prefers to receive bids on a fixed price cost per installation. If the licensing is by workstation or concurrent user, please include the cost of licensure by individual workstation or concurrent user and the expected number of workstations or concurrent users.*	
NCDC	
By Workstation or Concurrent User Number: Cost per:	
By Installation	
Software Maintenance (First year)	
Software Support (First year)	
Optimal Software Components / 3rd Party Tools: *List any additional software components included in the core System and what they are used for as described in 5.1. Only 3rd party items we are required to buy together with the System.*	
Specify:	

Initial Instrument Interfaces listed in RFP	
Number of instruments to be interfaced: Cost per instrument:	
Software Customization and Configuration Costs	
Initial customization and configuration of the software Expected number of days: Cost per day:	
Testing of software	
Cost of Report Design Expected number of days: Cost per day:	
Expected travel costs for customization and configuration, Number of trips planned to or within Georgia	
Other (specify)	
Other (specify)	
Network Administrator and Super User Training Costs	
Super User and Network Administrator Training	
Training materials for above Training(s)	
Other (specify)	
Other (specify)	
Installation and End User Training Costs: *List costs for training as described in 5.8.*	
NCDC	
Installation of software and configuration of server	
End User Trainer (minimum one week per site)	
Training materials for above Training	
Supportive Supervision (minimum two weeks per site)	
Other (specify)	
Other (specify)	
Other (specify)	
Other (specify)	
GAP Analysis: *Specify costs if any for a GAP Analysis described in 5.9.*	
Cost per day: Expected number of days:	
Other Costs	
Other (specify)	
Other (specify)	
Other (specify)	
TOTAL COST FOR ITEMS ABOVE	
OPTIONS (Not Required)	
Supply All Bar Code Printers and Scanners (Optional)	
Cost per Printer:	
Cost per Scanner:	
Post-installation Costs	
Technical Support:	
On-site (Cost per day)	

Remote support	
Travel costs and expenses included (Y/N), if not provide specifics	
Other (specify)	
Additional Instrument Interfaces	
Cost per Additional Instrument Interface	
Post-Installation Software Customization and Configuration	
Options:	
Post-Installation User Training	
Options:	
TOTAL COST FOR ITEMS ABOVE	
After Year 1	
Software Product License / Maintenance / System Updates	
Software Product License	
Software Maintenance	
System Updates	
Software Support	
Additional Software Components / 3rd Party Tools Fees	
Specify:	
TOTAL COST FOR ITEMS ABOVE	
Optional information:	
Phase 2 Installation: Provide a cost of licensing and deployment of the application at Phase 2 sites showing the cost for additional number of sites irrespective of the number of concurrent users. Indicate cost as of the date of proposal, for example, for Phase 2 including the 6 additional B/BTKL-PP sites (Reception, Virology, Parasitology and Bacteriology Laboratory sections), the estimated licensing cost per site is "the amount" as of the date submitted.	
TOTAL COST FOR ITEMS ABOVE	

APPENDIX F: APHL CONFLICT OF INTEREST DISCLOSURE STATEMENT
(FOR COMPLETION BY REVIEWERS ONLY – APPLICANTS DO NOT NEED TO COMPLETE)

Association of Public Health Laboratories

Conflict of Interest Disclosure Statement

Applicability: Disclosure of the following information is required of all Officers, Directors, committee members, staff members and other volunteers who have been designated and who have accepted responsibility to act on behalf of APHL ("APHL Personnel"). Please answer the following questions and, where indicated, include the same information for your immediate family members (your parents, your spouse or partner, your children and your spouse/partner's parents).

APHL will keep your completed disclosure statement in the corporate records of the association.

1. Please list the name, address, phone number, email address and type of business of your current employer. If you are self-employed, please note that below and provide us with the address, phone number, email address and type of business you operate.

_____

_____

_____

☐ Do you, or does any family member, currently serve as an officer, director, committee member, or other volunteer (or work as an employee of or a paid consultant to) any organization serving the interest of laboratory science or public health laboratories other than APHL or your state or local laboratory?

☐ **Yes** ☐ **No**

If yes, please list the organization(s) and provide detail on your or your family member's interest or position in the organization(s).

_____

☐ Do you, or any family member, have an existing or potential interest in, or compensation arrangement with, any third party providing goods or services to APHL, or with which APHL is currently negotiating?

☐ **Yes** ☐ **No**

_____

_____

_____

_____

If the answer is yes, please provide the name of the organization below and describe in detail the nature of the position held.

4. Please note any other financial or business interest you may have with any organization serving the interests of public health laboratories.

If you have none, please check this box: ☐

☐ Do you, or does any family member, have any other interest or affiliation that is likely to compromise your ability to provide unbiased and undivided loyalty to APHL, or that could come in conflict with your official duties as an Officer, Director, committee member, staff member or other volunteer who has been designated and who has accepted responsibility to act on behalf of APHL?

☐ Yes ☐ No

If you answered yes, please describe in detail below the nature of each such interest or affiliation.

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6. If you are currently aware of any actual or possible conflict of interest that might otherwise hamper your ability to serve APHL to your best ability and with the highest degree of care, loyalty and obedience – ***including any potential conflict you or a family member may have with one or more of the RFP applicants*** – please describe them in detail below.

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7. Do you agree that so long as you are an Officer, Director, committee member, staff member or other volunteer who has been designated and who has accepted responsibility to act on behalf of APHL you will immediately disclose to the other Directors and/or Officers or, for staff members, the Executive Director and/or General Counsel the nature of any interest or affiliation which you may hereafter acquire, which is in or is likely to become in conflict with your official duties with APHL?

☐ **Yes** ☐ **No**

YOU MUST READ THIS SECTION AND THEN SIGN BELOW

I acknowledge that I have received and read APHL's Fiduciary Responsibility and Conflict of Interest Policy (the Policy). I have listed all my relevant fiduciary responsibilities and affiliations, and I have identified any actual or potential conflict of interest on this Disclosure Statement and I agree to abide by the Policy. I understand that it is my responsibility to inform APHL in writing of any change in circumstances relating to the Policy and this Disclosure Statement.

Signature: Date:

Printed Name:

APHL Fiduciary Responsibility and

Conflict of Interest Policy

1. Policy Statement and Purpose

The members of the APHL Board of Directors understand the importance of serving APHL to the best of their ability and with the highest degree of obedience, loyalty and care. Accordingly, the Board adopts the following policy for APHL Officers and Directors, all staff, committee members, and other volunteers who have been designated and who have accepted responsibility to act on behalf of APHL ("APHL Personnel").

2. Individual Duty and Annual Disclosure

APHL Personnel will avoid any conflict of interest with APHL. APHL Personnel will not profit personally from their affiliation with APHL, or favor the interests of themselves, relatives, friends or other affiliated organizations over the interests of APHL. As used in this Policy, "Conflict of interest" includes any actual, apparent, and potential conflict of interest.

Upon commencing service with APHL, each APHL Personnel will file with the Board an annual statement disclosing all material business, financial, and organizational interests and affiliations they or persons close to them have which could be construed as related to the interests of APHL or the profession of public health laboratory science. Each APHL Personnel has an obligation to make an additional disclosure if a conflict of interest arises in the course of the individual's service to APHL, whether arising out of his/her employment, consulting, investments, or any other activity. These disclosures will be documented promptly in writing and recorded in the Board minutes and corporate records.

3. Procedure

Whenever APHL considers a matter, which presents an actual, apparent, or potential conflict of interest for APHL Personnel, the interested individual will fully disclose his/her interest in the matter, including the nature, type, and extent of the transaction or situation and the interest of the individual or that individual's relatives, friends or other affiliated organizations. The Board, after consultation with counsel as appropriate, will determine whether an actual and material conflict exists and, if so, what is the appropriate course of action under this policy and the Board vote will be recorded in the minutes.

Any Board member having a conflict of interest must either (i) voluntarily abstain from and be disqualified from participation in all deliberation and voting on all Board actions relating to the situation or matter that gives rise to the conflict of interest, or (ii) ask the Board to determine whether an apparent or potential conflict of interest is considered by the Board to be an actual and material conflict. In the event that the Board member in question requests that the Board evaluate the apparent or potential conflict, that Board member will abstain and be disqualified from participating in (and voting on) the determination of whether the issue presents an actual and material conflict. If the Board determines that an actual and material conflict exists, the Board member in question will abstain from all voting on, and will be disqualified from participation in all deliberation concerning all Board actions relating to the conflict of interest. The vote will be recorded in the minutes.

These procedures will neither prevent the interested individual from briefly stating his/her position on the matter, nor preclude him/her from answering pertinent questions of Board members, since his/her knowledge may be of assistance to the Board's deliberations.

APHL Personnel must be cautious and protective of the assets of APHL and insure that they are used in the pursuit of the mission of APHL. The association's policy requires APHL Personnel to avoid

transactions in which APHL personnel may have a significant financial interest in any property which APHL purchases, or a direct or indirect interest in a supplier, contractor, consultant, or other entity with which APHL does business. The Board, after consultation with counsel as appropriate, will determine whether an actual and material conflict exists and, if so, determine whether the transaction is nonetheless favorable to APHL before considering whether to approve it.

4. Other Duties and Obligations

Whenever any APHL Personnel discovers an opportunity for business advantage which is relevant to the activities of APHL, the opportunity belongs to APHL and the individual must present this opportunity to the Board. Only once the Board determines not to pursue the matter and relinquishes the opportunity may the individual consider it a matter of possible personal benefit. APHL Personnel may not accept favors or gifts exceeding $75.00 from anyone who does business with APHL.

All APHL Personnel will keep confidential those APHL matters designated confidential. APHL Personnel are prohibited from disclosing information about APHL to those who do not have a need to know or whose interest may be adverse to APHL, either inside or outside APHL, and are prohibited from using in any way such information for personal advantage to the detriment of APHL.

All APHL Personnel who participate in APHL activities, including committee activities and international consultation activities, must be adequately prepared to fully participate as their position descriptions require and will do so in accordance with the applicable laws and regulations of their respective state or territory and APHL's Articles of Incorporation, Bylaws, and corporate policies. The APHL Board will read and understand the association's Articles of Incorporation, Bylaws, corporate policies and financial statements, and routinely verify that all state, federal, and local tax payments, registrations and reports have been filed in a timely and accurate manner.

Board members will never exercise authority on behalf of APHL except when acting in meetings with the full Board or the Executive Committee or as authorized by the Board. If any member of the Board has significant doubts about a course of action of the Board, he or she must clearly raise the concern with the Executive Director and the Board and, when appropriate, seek independent expert advice.